In re: Appln No. 09/716,146
Attorney Docket: 6006-018
Customer No. 29,335

Remarks/Arguments:

In the Office Action dated October 28, 2005 the Examiner rejected Claims 16, 20, and 26-28 under 35 U.S.C. 102(e) as being anticipated by Brown, rejected claims 16, 26, and 27 under 35 U.S.C. 102(b) as being anticipated by Monaco, rejected claims 16, 20, and 26-28 under 35 U.S.C. 102(b) as being anticipated by the Yan, and rejected Claims 16, 26, and 27 under 35 U.S.C. 102(b) as being anticipated by Buirge. No other basis of rejection was stated of record.

Background of the Law

In order to establish a proper anticipation under 35 U.S.C. §102, each and every element of the claimed invention must be disclosed in a single prior art reference. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990). The claimed elements must either be inherent or disclosed expressly in the single prior art reference. *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 7 USPQ2d 1057 (Fed. Cir. 1988) and must be arranged as in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989). The absence from the reference of any claimed element necessarily negates anticipation. *Kloster Speedsteel AB. v. Crucible Inc.*, 793 F.2d 1565, 220 USPQ 81 (Fed. Cir. 1986). Anticipation can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best,* 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) and MPEP §2112.01.

Summary of Amendments

Applicant has amended Claim 16 to more clearly state and define subject matter regarded as the invention. his Amendment does *not* raise new issues requiring further search or consideration and must be entered and considered by the Examiner. Specifically, original claim 12 was considered by the Examiner and included the limitation that the structural elements be fabricated of a vacuum deposited metal. Additionally, the present amendments do not add new matter to the application. Applicant respectfully submits that the newly submitted Claims define patentable subject matter over the prior art of record in this application.

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Remarks

Response to Examiner's Previous Remarks

Examiner has categorically misinterpreted claim 16 and the Brown reference as a product-by-process claim. Examiner has cited to MPEP §2113 that Brown's device is the same final product; however, neither Applicant's claim 16 nor Brown's device is a product by process claim. Clearly, Claim 16 is an apparatus claim comprising structural elements, and nowhere in the claim does it state that the endoluminal stent is to be made by a specific process. Rather, Claim 16 has the specific structural limitations; therefore, Applicant respectfully requests that the Examiner treat Claim 16 as a product claim. More so, Brown has not claimed a product-by-process and Brown does not even disclose a process for making the stent. Lastly, Applicant has amended Claim 16 to indicate the clear structural limitation of layers made from deposited metal, which gives Claim 16 different physical characteristics than those taught or suggested by Brown. See below.

Moreover, Examiner has stated that "although the structural elements are claimed to be fabricated of metal, the "layers" are not required by the claim to be metal; that is the structural elements as a whole need only comprise metal and may include other materials as well". The Examiner has misconstrued Claim 16, because Claim 16 explicitly states that the "structural elements *are* fabricated of a metal", and does not state that the structural elements "comprise metal". The Examiner's claim interpretation of Claim 16 adds the additional element that the layers be fabricated of a metal *or a polymer*. Applicant did not use comprising to indicate what the structural elements were fabricated of. ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986), see MPEP §2111.03. Moreover, the named element "are fabricated of a metal" is essential and other elements may not be added, because it would form a construct outside the scope of the claim, i.e. structural elements formed from a plastic. Finally, Applicant has amended Claim 16 to clearly indicate that the layers are made from a *deposited* metal, as to prevent further confusion of the claim and to indicate that Brown does not have nor teach a device having layers or that the layers are made of vacuum deposited metal.

The Brown Reference Does Not Anticipate Claims 16, 20, and 26-28 because the Brown Reference Does Not Contain Layers Fabricated from a Deposited Metal

Applicant has amended Claim 16 to indicate that the structural elements, as well as base and top layers, are fabricated of a *vacuum deposited* metal. As noted above, this Amendment does *not* raise new issues requiring further search or consideration and must be entered and considered by the Examiner. Original claim 12 included the limitation that the structural elements be fabricated of a vacuum deposited metal and was duly considered by the Examiner during prosecution of this application.

There is no teaching in the Brown reference that the stent structure described therein possesses possess the characteristics of the stent in Claim 16. See MPEP §2112.01, if the PTO has a basis that the claimed product and a prior art device are the same, such basis is rebutted by showing that the prior art product does not possess the same characteristics of the claimed product. Applicant notes that the commonly assigned U.S. patent application 09/443,929 (now U.S. Patent No. 6,379,383 (hereinafter patent '383)) was incorporated by reference into the current application. Pg. 11, lines, 7-8. Patent '383 teaches that the homogenous surface properties of a *deposited metal* give a stent specific surface energy and electrostatic charges across the blood-contact surface, as well as yielding a metal having *controlled heterogeneities across the tissue-contact surface.* Col. 5, lines 7-9, and lines 20-30. Conventional stents made from bulk metals, as disclosed in the Brown reference, have uncontrolled surface and subsurface heterogeneity resulting from the manufacturing processes. Col. 2, lines 21-22 of the '383 patent. Surface and subsurface inclusions consequently form, which have an unpredictable and uncontrolled heterogeneous surface. Col. 2, lines 24-32. Thus, the inclusions interrupt the regular distribution pattern of surface free energy and electrostatic charge on the metal surface. Col 2, lines 34-37. Thus, vacuum deposited metals have physical characteristics which are not found in conventionally fabricated metals. The inclusion of "vacuum deposited" to modify "metal" is, therefore, not a process limitation. Therefore, the Brown reference made by non-deposited metals, does not possess the controlled heterogeneity characteristics of Claim 16's deposited metal, as to anticipate Claim 16.

Accordingly, based upon the foregoing express disclosure and teaching of the Brown reference, express claimed elements of the presently pending claims are clearly not present in the reference, and consequently, inappropriate as a basis for anticipation under 35 U.S.C. §102(e).

The Monaco reference does not Anticipate Claims 16, 26, and 27 because the Monaco Reference Does Not Contain Layers Fabricated from a Deposited Metal

Applicant has amended Claim 16 to indicate that the structural elements, as well as base and top layers, are fabricated of a deposited metal. The Monaco reference does not disclose the structural elements or layers thereof that are fabricated of a *vacuum deposited* metal, but discloses the use of non-deposited titanium or stainless steel, which has different physical and mechanical characteristics from the claimed deposited metal, as noted above. Monaco's metallic housings are fabricated by conventional milling procedures (pg. 24, lines 16-17), which has an uncontrolled and unpredictable heterogeneity characteristic. '383 Patent, Col. 1, Lines 35-40, Col. 2, lines 24-32. And even if the Monaco reference were to be fabricated by vacuum deposition of metal, it does not necessarily follow that the metal is radially expandable. If the Examiner is claiming that the metal is inherently expandable, then the Examiner must come forward with evidence and not use Applicant's own disclosure. See MPEP §2112.

Accordingly, based upon the foregoing express disclosure and teaching of the Monaco reference, express claimed elements of the presently pending claims are clearly not present in the reference, and consequently, inappropriate as a basis for anticipation under 35 U.S.C. §102(b).

The Yan reference does not Anticipate Claims 16, 20, and 26-28 because the Yan Reference Does Not Contain Layers Fabricated from a Deposited Metal

Applicant has amended Claim 16 to indicate that the structural elements, as well as base and top layers, are fabricated of a *deposited* metal. Yan discloses *sintered* metallic structural members. Col. 4, lines 1-3. As discussed previously, the sintered metallic structural members do not contain the characteristics of deposited metal. Sintering is a conventional method of making a stent, where the metal has particles bonded together by heating to temperatures slightly below the melting point of the metal. Col. 4, lines 7-9. Such heat treatment results in chemical segregation to give an uncontrolled surface and subsurface heterogeneity. '383 patent, Col 2.,

Lines 21-33. Therefore, Yan does not show or teach layers fabricated from a deposited metal, which gives different characteristics to the claimed product.

With regard to Claim 20, Yan does not disclose a degradable plug residing *within* the plurality of pores. The Yan reference discloses a coating that is *applied* to the sintered metal, (Col. 8, line 49), the polymeric film *coats* a sintered metal stint (Col 9. lines 16-18), and Figure 11 all suggest that the polymeric film is not *within* the pores, but rather, the film covers the pores with a thin skin or membrane, i.e. by spreading over the surface of the pores. Therefore, Yan does not disclose each and every limitation of Claim 20.

Accordingly, based upon the foregoing express disclosure and teaching of the Yan reference, express claimed elements of the presently pending claims are clearly not present in the reference, and consequently, inappropriate as a basis for anticipation under 35 U.S.C. §102(b).

The Buirge reference does not Anticipate Claims 16, 26, and 27 because the Buirge Reference Does Not Contain Layers Fabricated from a Deposited Metal

Applicant has amended Claim 16 to indicate that the structural elements, as well as base and top layers, are fabricated of a *deposited* metal. Generally, the Buirge reference discloses metals such as stainless steel and nitinol, which are not deposited but rather dip-coated or cast-sheeted. Col.4, lines 32-63. Such metals do not have the characteristics of deposited metal, as noted above. Stainless steel and nitinol are customarily used in manufacturing stents, which have uncontrolled and unpredictable heterogeneity characteristics. '383 Patent, Col. 1, Lines 35-41, Col. 2, lines 24-32.

Moreover, the Buirge reference does not disclose a void space, because intermediate layer 14 is a therapeutic containing matrix (Col. 4, lines 8-10) and intermediate layer 14 comprises either a mixture swelling/dissolving natural or synthetic material. Such a "layer" is not a void, because it is a thickness of material containing matter.

Accordingly, based upon the foregoing express disclosure and teaching of the Buirge reference, express claimed elements of the presently pending claims are clearly not present in the reference, and consequently, inappropriate as a basis for anticipation under 35 U.S.C. §102(b).

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Summary

Accordingly, Applicant submits that the pending claims are patentably distinct from and over the art cited and of record. Favorable reconsideration of the rejection of the pending claims is solicited.

This Amendment Letter is being concurrently filed with a Transmittal Letter, which includes a claim fee calculation and any applicable requests for extension of time that may be required for the proper presentation and consideration of the present amendments. While no additional fees other than those stated in the Transmittal Letter are believed to be required in connection with the filing of this amendment, the Director is hereby authorized to deduct any such fees from Deposit Account No. 18-2000 of which the undersigned is an authorized signatory.

Applicant solicits the Examiner's favorable reconsideration of the rejections and objections of record and submits that the presently pending claims are allowable over the art cited and of record, and therefore requests that Claims 16, 20, and 26-28 be allowed. Should the Examiner find that there are any outstanding matters, which are susceptible of resolution by telephone interview; the Examiner is invited to telephone the undersigned to discuss the same.

Respectfully submitted,

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